

**REMARKS**

**I. STATUS OF THE CLAIMS**

Prior to this amendment, claims 8-14, 30, and 45-51 were pending in this application. With this amendment, claims 10 and 30 are amended, claims 50-51 are canceled, and new claims 52 and 53 are added. Applicants reserve the right to pursue any of the canceled claims in a separate application. Accordingly, claims 8-14, 30, 45-49, 52, and 53 are currently pending.

Support for the claim amendments can be found throughout the original specification as filed. For example, support for the amendment to claim 30 can be found, e.g., at page 7, paragraph [026]. Support for new claim 52 can be found, e.g., at page 6, paragraph [018].

Support for the proviso in new claim 53 can be found throughout the specification and examples. Adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993) (citation omitted). Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an applicant had possession of the concept of what is claimed. *Id.* In the present case, the specification repeatedly described and exemplifies the claimed compositions. Nowhere does the specification recite that the inventive compositions comprise or even could comprise antifungal imidazole derivatives. Accordingly, the originally-filed disclosure would have conveyed to one having ordinary skill in the art the concept of hydrating brittle toenails or fingernails using compositions that did not include antifungal imidazole derivatives.

Accordingly, no new matter is added by this amendment. Applicants therefore respectfully request that the Examiner enter these amendments.

**II. OBJECTION TO THE AMENDMENT TO THE SPECIFICATION**

The Examiner maintains an objection under 35 U.S.C. § 132(a) to the amendments to paragraphs [010] and [022] of the specification filed on September 20, 2005, as allegedly introducing new matter. Office Action at page 2. Applicants respectfully traverse this rejection. Nevertheless, to expedite prosecution, Applicants

have amended paragraphs [010] and [022] to match those filed in the original specification filed on September 20, 2005.

### **III. REJECTIONS UNDER 35 U.S.C. § 112**

The Examiner rejected claim 51 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, allegedly because “the boundaries of “larger” in the amount of urea that is larger than the amount of water is not clear/not known.” Office Action at page 4. Claim 51 has been canceled, thus rendering this rejection moot.

### **IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)**

#### ***1. Rejections over Laugler et al. (GB 2 202 743)***

Claims 9-12, 30, and 45-50 are rejected under 35 U.S.C. § 103(a) as obvious over Laugler *et al.* (GB 2 202 743; “Laugler”). Applicants respectfully traverse this rejection.

First, the basis for the rejection was the assertion that “the percent amount of urea taught by Laugler at 1-20% overlaps the claimed range in claim 30,” which was from 15 to 35% by weight. Office Action at pages 5, ¶¶ 6 and 7. However, independent claim 30 has now been amended to recite urea concentrations from 25 to 35 percent by weight. That range does not overlap at all with the range disclosed by Laugler. For that reason alone, this rejection should be withdrawn.

Second, Laugler does not teach or suggest a method of hydrating brittle toenails or fingernails comprising applying to brittle toenails or fingernails an aqueous solution as presently claimed. Rather, Laugler is drawn to solving a different problem (providing an antifungal composition) using a different composition (e.g., comprising at least one antifungal imidazole derivative) in a different form (“in the form of a lotion, gel (a thickened composition) or varnish” (Laugler at page 2, 4<sup>th</sup> para), but not a solution) from that presently claimed. Accordingly, there would have been no reason to modify

Laugler's compositions at all, let alone to modify them in the manner necessary to arrive at the present compositions.

Third, although a prior art range may, in certain cases, be optimized through routine experimentation, the particular parameter to be varied must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of that variable may be characterized as routine experimentation. M.P.E.P. § 2144.05. Here, the Examiner asserted that "[o]ne having ordinary skill in the art would have been motivated to adjust the amount of urea [in Laugler's compositions] to obtain desired level of treatment of fungal infection (onychomycosis)." Office Action at page 8. However, Laugler uses urea as solubilizing agent, not as an active agent. Laugler at page 2, second full para. Thus, there is no basis in Laugler to suggest that urea was recognized as a result-effective variable for treatment of fungal infection. And, although urea affects the dissolution of the active agent(s) in Laugler, the optimum range for such dissolution was determined by Laugler to be 1 to 20% by weight. Accordingly, there would have been no reason to modify the urea concentration in Laugler's compositions.

In fact, Laugler teaches away from increasing the urea concentration, explicitly stating "the weight of the urea present not exceeding the weight of water present." See, e.g., Laugler at page 2, third para. The weight of the water in Laugler ranges from 5 to 20% by weight. Accordingly, Laugler **expressly teaches away** from increasing the concentration of urea to that of the claimed range (25 to 35% by weight) since that would exceed the weight of the water. Accordingly, Applicants respectfully request the withdrawal of this rejection.

New claim 52 recites that the aqueous solution comprises water in an amount from 30% by weight to 60% by weight based on the weight of the entire solution. Laugler, which discloses a concentration a range of 5 to 20% by weight, fails to render that claim obvious. None of Laugler's Examples uses a water concentration beyond the disclosed/claimed range and, in fact, they contain less than or equal to 10% by weight water. Laugler at pages 5 and 6. Indeed, Laugler's compositions comprise "at least 1% by weight . . . of miconazole nitrate or econazole nitrate" (Laugler at page 2, 3<sup>rd</sup> full para). And Laugler explicitly states that both are "insoluble in water." Laugler at page

1, 4<sup>th</sup> para. Accordingly, there would have been no reason to increase the concentration of water in Laugler's compositions, as Laugler teaches away from doing so.

New claim 53 expressly excludes antifungal imidazole derivatives from the aqueous solution. In contrast, Laugler's composition requires from 1 to 2% by weight of at least one antifungal imidazole derivative as the active agent(s). Accordingly, Laugler teaches away from claim 53.

For at least those reasons, Applicants respectfully request withdrawal of this rejection.

***2. Rejection over Laugler in view of Crandall (US 5,639,740)***

The Examiner maintained the rejection of claims 8, 13, 14 and 30 under 35 U.S.C. § 103(a) as obvious over Laugler in view of Crandall (US 5,639,740). Office Action at page 7. Applicants respectfully traverse this rejection.

Crandall is relied upon for the disclosure of a composition applied to cracked fingernails or toenails comprising lactic acid. Office Action at pages 7-8. That disclosure fails to remedy the deficiencies in Laugler that are discussed above. Accordingly, Applicants respectfully request withdrawal of this rejection.


**V. CONCLUSION**

In view of the amendments and remarks herein, Applicants respectfully request reconsideration of this application. Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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